

Docket No.: 101896-719
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Edward B. Zalenski et al.

Application No. 10/750,173

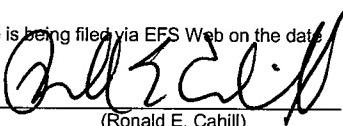
Confirmation No. 5023

Filed: December 31, 2003

Art Unit: 3733

For: INSERTER INSTRUMENT AND IMPLANT
CLIP

Examiner: Annette R. Reimers

I hereby certify that this correspondence is being filed via EFS Web on the date shown below.
Dated: October 24, 2007 Signature: 
(Ronald E. Cahill)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST	1
II.	RELATED APPEALS AND INTERFERENCES.....	1
III.	STATUS OF CLAIMS	1
IV.	STATUS OF AMENDMENTS	1
V.	SUMMARY OF CLAIMED SUBJECT MATTER	1
A.	The Problem Addressed by the Invention Is the Cumbersome and Sometimes Hazardous Manipulation and Insertion of a Spinal Implant.....	1
B.	The Invention Solves the Problem by Providing an Implantation Device to Facilitate the Easy, Safe, and Efficient Insertion of a Spinal Implant	2
C.	The Single Independent Claim at Issue.....	4
VI.	GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	4
VII.	ARGUMENT	4
A.	35 U.S.C. §102(e) Rejection Over Markworth	4
1.	The Markworth Reference.....	5
2.	The Anticipation Rejection	6
3.	Markworth Does Not Disclose the Features of Claim 1	9
a.	Markworth Fails to Disclose an Outer Sleeve that is Mechanically Coupled to a Frame as Recited in Element (ii)	10
b.	Markworth Fails to Disclose an Inner Shaft Having a Grabber as Recited in Element (iii).....	11
c.	Markworth Fails to Disclose an Inner Shaft Slidably Disposed Within an Outer Sleeve as Further Recited in Element (iii).....	12
d.	Markworth Fails to Disclose that Actuation of a Trigger is Effective to Extend a Grabber from an Outer Sleeve to Thereby Release an Implant as Further Recited in Element (iii).....	13
e.	Markworth Fails to Disclose a Retaining Element for Directing the Grabber Toward a Closed Position as Recited in Element (iv)	14
f.	Markworth Fails to Disclose a Grabber that is Substantially Contained Within an Outer Sleeve When a Trigger is Released as Recited in Element (iv)	15
4.	Several Dependent Claims are Further Separately Patentable Over Markworth	16

a.	Dependent Claim 3 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Knob Mechanically Coupled to an Outer Sleeve and Causing the Outer Sleeve and Inner Shaft to be Rotated About the Frame.....	17
b.	Dependent Claim 5 is Separately Patentable Over Markworth Because Markworth Fails to Disclose at Least One Protrusion on an Outer Sleeve	17
c.	Dependent Claim 6 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Depth Control Member Slidably Coupled to an Outer Sleeve	17
d.	Dependent Claims 12, 13, and 14 are Separately Patentable Over Markworth Because Markworth Fails to Disclose a Grabber With at Least One Marking to Identify the Position of the Implant.....	18
e.	Dependent Claim 15 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Grabber that is Removably Coupled to an Inner Shaft.....	18
B.	35 U.S.C. §103(a) Rejection Over Markworth in View of Lim.....	18
VIII.	CONCLUSION.....	20
	CLAIMS APPENDIX.....	1
	EVIDENCE APPENDIX.....	6
	RELATED PROCEEDINGS APPENDIX	7

I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc., a Johnson & Johnson company. DePuy Spine, Inc. of Raynham, Massachusetts derives its rights in this application by virtue of an assignment of the application from Edward B. Zalenski et al., to DePuy Spine, Inc., of Raynham, Massachusetts as recorded at Reel 015347, Frame 0080.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-30 are currently pending in the present application, with claims 8, 10, 14, and 16-30 withdrawn from consideration. According to the Final Office Action mailed on March 7, 2007, each of claims 1-7, 9, 11-13, and 15 stand finally rejected. Accordingly, claims 1-7, 9, 11-13, and 15 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The systems and methods described in the pending application generally relate to a device for implanting a prosthesis implant, including embodiments where the prosthesis is a multi-piece spinal disc prosthesis that can be provided inside a clip. The present invention additionally provides for the safe, one-handed insertion of such a prosthesis. To fully understand the claimed invention, it is first necessary to appreciate the state-of-the-art at the time of Appellant's invention, which represents the background against which the claimed invention was developed.

A. The Problem Addressed by the Invention Is the Cumbersome and Sometimes Hazardous Manipulation and Insertion of a Spinal Implant

Spinal surgery involves many challenges as the long-term health and mobility of the patient often depends on the surgeon's technique and precision. One type of spinal surgery involves the removal of a damaged disc that is located between adjacent vertebral bodies. Procedures are known in which the damaged disc is then replaced with a spinal disc prosthesis or

spinal fusion cage. These artificial discs and cages have protrusions for engaging adjacent vertebral bodies and to aid in the initial fixation of the implant. These protrusions are often sharp and can injure the surgeon's hand, if contacted, during implantation. [See Para. [0002] of the Published Application.]

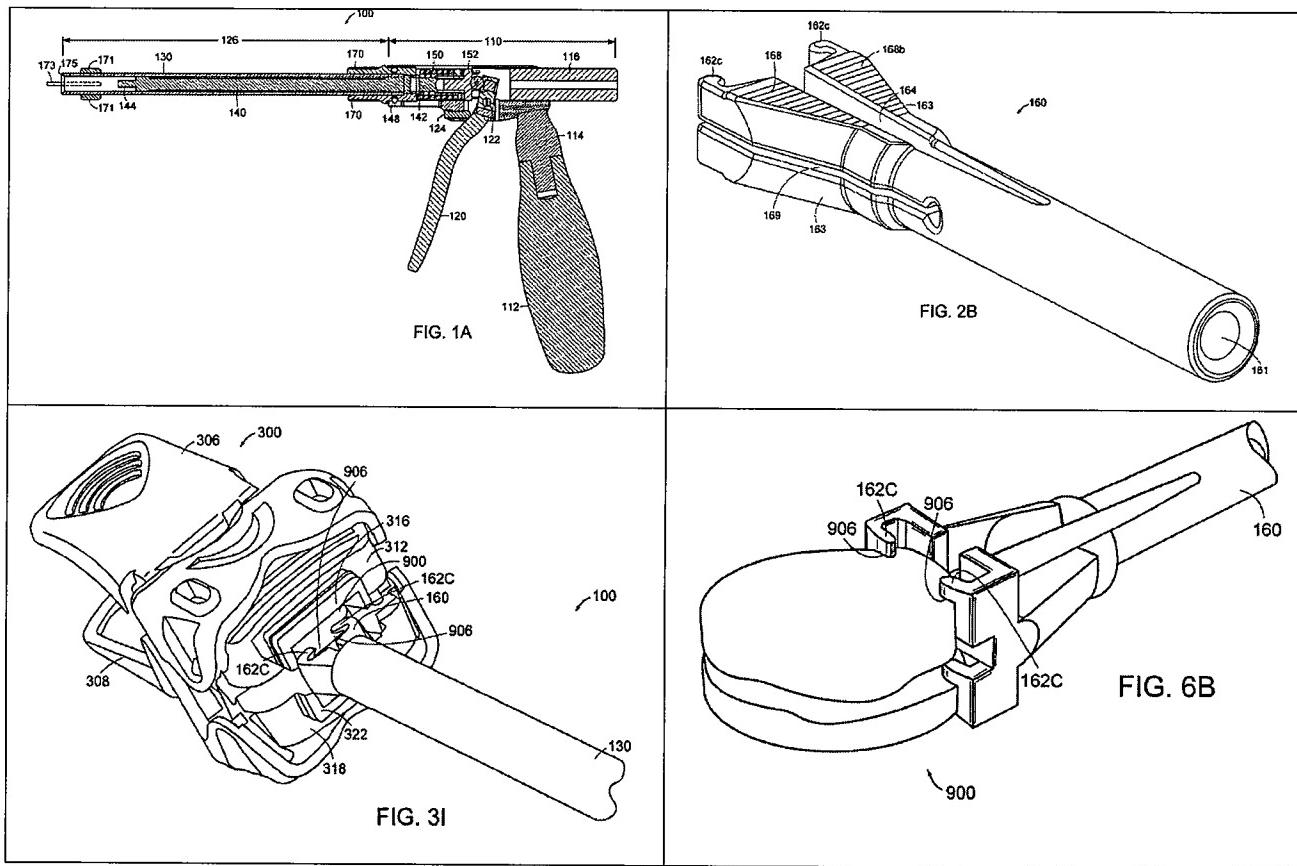
Further, the insertion of a spinal disc prosthesis or spinal fusion cage presents a risk of injury to the patient if the adjacent vertebral bodies are not separated to the appropriate degree or if the bodies collapse upon each other once the damaged disc is removed. In addition, the spinal implant must be properly positioned to prevent over-insertion posteriorly or under-insertion anteriorly, which can lead to further injury to the patient. Tools have been developed to address these problems, but the use of these tools can prove cumbersome for the surgeon and hazardous to the patient. Operation of these tools can require two hands, and they do not provide the ability to simultaneously grasp all parts of a multi-piece prosthesis during manipulation and insertion. [See Para. [0003]-[0004] of the Published Application.]

B. The Invention Solves the Problem by Providing an Implantation Device to Facilitate the Easy, Safe, and Efficient Insertion of a Spinal Implant

The claimed invention addresses these issues by providing an implantation device for assisting the safe, one-handed insertion of a spinal implant into a prepared disc space. The implantation device described and claimed is capable of simultaneously grasping and holding all elements of a multi-piece spinal disc prosthesis during manipulation and implantation. As such, the invention can reduce the amount of time required to complete the surgical procedure. In general the claimed implantation device includes (i) a frame having a trigger mechanism, (ii) an outer sleeve mechanically coupled to the frame, (iii) an inner shaft having a grabber for mechanically engaging the implant, and (iv) a retaining element for directing the grabber toward a closed position.

Figure 1A below illustrates one embodiment of the claimed implantation device. The instrument 100 includes a frame 110 with an actuator assembly 126 disposed distally to the frame. The frame 110 includes a handle 112 and a trigger 120. The actuator assembly 126 includes inner shaft 140 and outer sleeve 130. A "grabber" 160 (one embodiment of which is illustrated in isolation in Figure 2B, below) is provided on the distal end of the inner shaft 140 for grasping the prosthesis.

The distal end of the device 100 is shown in Figure 3I below, engaged to a spinal disc prosthesis 900 that has been enclosed within a clip 300 to hold its components in a proper orientation for grabbing by the implantation device and for implantation. In Figure 6B, the clip 300 has been removed and the distal end of the device is shown “grabbing” the multi-piece spinal disc prosthesis 900 – now ready for implantation.



C. The Single Independent Claim at Issue

The present application has a total of 12 claims, one of which is independent.

Independent claim 1, which was amended during prosecution, recites an implant device which includes a frame having a trigger mechanism, an outer sleeve mechanically coupled to the frame, and an inner shaft having a grabber for mechanically engaging the implant. The inner shaft is slidably disposed along a major axis within the outer sleeve whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant. The implant device further includes a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Two grounds of rejection were provided in the final rejection, and Appellants ask the Board to review both on appeal. These are:

- A. Claims 1-7, 9, 11, 12, and 15 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0199872 of Markworth et al. (“Markworth”);
- B. Claim 13 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Markworth in view of U.S. Patent Publication No. 2005/0055031 of Lim.

VII. ARGUMENT

Appellants address each of the grounds of rejection in turn below.

A. 35 U.S.C. §102(e) Rejection Over Markworth

Markworth is critical to the rejections made – it is cited as an anticipatory reference for 11 of the 12 pending claims and it is the primary reference in the combination of art cited against the twelfth pending claim. Markworth, however, discloses a different device that is configured in a way that is the diametric opposite of relevant claim elements. The Markworth device is suited to grasp a pedicle screw on the outside, and uses an inner pusher element to force a spinal fixation rod into a seat within the head of the pedicle screw. Accordingly, while Markworth has a frame having a handle and a trigger – everything else about it is different, including that when you squeeze the trigger of the Markworth device, that pushing element goes forward – the element is not retracted as it is in the configuration claimed.

As the disclosure of the Markworth reference is crux of this appeal, Applicants start with a review of this disclosure illustrating what the Markworth device is and how it works.

I. The Markworth Reference

Markworth provides an orthopedic device for urging a spinal fixation rod into a slot in the head of a pedicle screw. Markworth has a handle 218 which is fixedly attached to a body 200. [Para. 44.] A trigger 500 connects to a slide 300 to connect the slide to the body 200. [Para. 48.] A sleeve 400 is connected to the distal end of slide 300. [Para. 50.] In use, fingers 206 provided on the distal end of body 200 engage or grip the head of a pedicle screw. The trigger 500 is then squeezed toward the handle 218, as illustrated in Figures 1A and 1B below, so that slide 300 slides distally on body 200, pushing sleeve 400 distally, which in turn pushes the spinal fixation rod into the head of the pedicle screw. [Para. 51.]

FIG. 1A

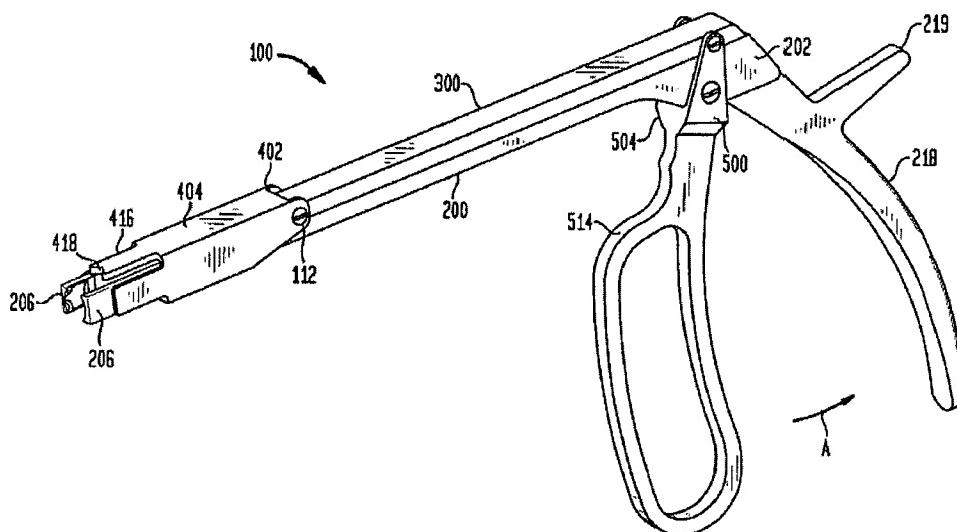
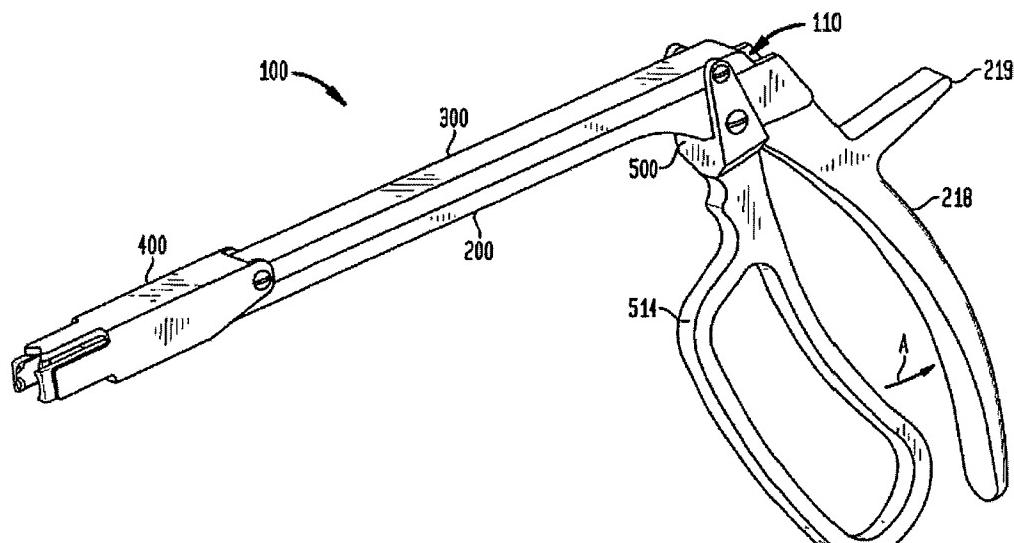


FIG. 1B



As further illustrated in Figures 6A and 6B, a spring 600 and ratchet 700 are provided to bias the trigger 500 to its "unpulled" position in which the sleeve 400 is retracted:

FIG. 6A

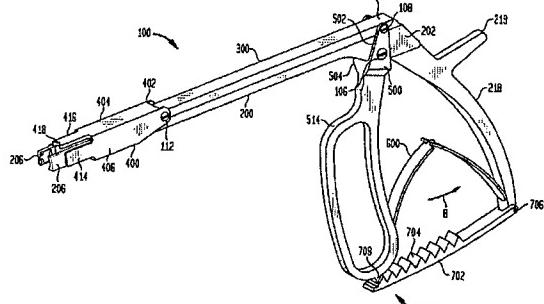
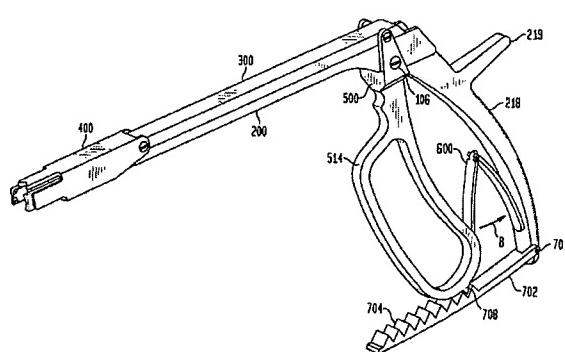


FIG. 6B



2. *The Anticipation Rejection*

The Examiner rejects claims 1-7, 9, 11, 12, and 15 pursuant to 35 U.S.C. §102(e). In particular, the Examiner states:

Markworth et al. disclose various embodiments of an implant implantation device comprising a frame having a trigger mechanism, 514, an outer sleeve, 400, mechanically coupled to the frame, an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant, wherein

the inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant, and a retaining spring element, 600, for directing the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released (see figures 6A, 6B, 7A and 7B). The device further includes a drag adjustment screw, 108, rotatably coupled to the frame for providing tension between the trigger mechanism and the inner shaft, and a including a depth control member, 200, slidably coupled to the outer sleeve, wherein the depth control member provides a predetermined insertion depth of the implant (see figures 6A, 6B, 7A and 7B). The device also includes a protrusion, 112, on the outer sleeve for slidably engaging a distraction instrument (see figures 6A, 6B, 7A and 7B). Markworth et al. further disclose a knob, 712, mechanically coupled to the outer sleeve, wherein the knob is capable of causing the outer sleeve and the inner shaft to be rotated about the frame (see figures 7A and 7B and paragraphs 0057-0060). The grabber includes grabber tips for mechanically engaging an implant wherein the grabber tips include a first pair of slots for engaging a first engagement tab of the implant and a second pair of slots for engaging a second engagement tab of the implant and wherein a sizing slot is located between the first pair of slots and the second pair of slots to allow for a variation of tab and slot dimensional differences (see figure 1C). The grabber further includes markings, e.g. 111, to identify a position of an implant, and the grabber is capable of being removably coupled to the inner shaft (see figures 6A, 6B, 7A and 7B).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Markworth et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With regard to the last paragraph of the rejection, the Examiner does not identify which claim recitation is a "statement of intended use" or "other functional statement." Appellants have never argued, and do not now argue, that a "statement of intended use" differentiates the

present claims from the Markworth reference. The different use of the two instruments does, however, explain why the instruments are so different – and why certain of the Markworth elements are configured in a way that is diametrically opposed to the recitations of claim 1 – they are configured to do completely different things.

Further, the Examiner is wrong as a matter of fact. As explained in detail below, the device of Markworth is not “capable of being used as claimed.” Rather, the only way in which the Markworth device can be used is diametrically opposed to the claim recitations.

Still further, the Examiner is wrong as a matter of law. To the extent any of the claim recitations relied upon above might be considered by the Examiner to be functional, the law is quite clear that when the prior art device is not capable of performing the recited function, it does not anticipate. As the MPEP and the cases it cites make clear, not only is the use of functional language not improper, but when considered in context through the eyes of a person of ordinary skill in the art, it may serve to precisely define the structural attributes of the claimed invention:

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). ***There is nothing inherently wrong with defining some part of an invention in functional terms.*** Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, ***for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.*** A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. . . .

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" ***serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.*** *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

(MPEP, § 2173(g) Functional Limitations; emphasis added.) Here, a person of ordinary skill in the art would have no problem understanding exactly the structural attributes of the interrelated component parts of the claimed assembly. As will be made clear below, the Markworth device cannot meet the claim recitations precisely because of those structural attributes of the interrelated component parts of the claimed assembly referred to in the cases.

3. *Markworth Does Not Disclose the Features of Claim 1*

Independent claim 1 recites an implant device which includes a frame having a trigger mechanism, an outer sleeve mechanically coupled to the frame, and an inner shaft having a grabber for mechanically engaging the implant. The inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant. The implant device further includes a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.

The anticipation case for claim 1 as laid out by the Examiner in the Final Office Action is as follows:

<i>Claim 1 Element:</i>	<i>Correspondence to Markworth per the Office Action:</i>
i) a frame having a trigger mechanism;	“a frame having a trigger mechanism, 514,”
ii) an outer sleeve mechanically coupled to the frame;	“an outer sleeve, 400, mechanically coupled to the frame,”
iii) an inner shaft having a grabber for mechanically engaging an implant, the inner shaft slidably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant; and	“an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant,” “wherein the inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve,” “whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant, and”
iv) a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.	a retaining spring element, 600, for directing the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released (see figures 6A, 6B, 7A and 7B).

Because the intended function of Markworth is so different from the claimed device, its structure is so different as to be exactly the opposite of the claimed configuration – making

anticipation by Markworth impossible. Not only must “each and every element as set forth in the claim” be found in the prior art reference for anticipation to lie, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), but the elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *See, also*, MPEP § 2131. To the extend that Markworth has elements that could generally correspond to those recited in claim 1 – the Markworth elements are arranged in a way that is the opposite of and incompatible with the claim.

The arguments below are arranged according to the element numbers from the chart of the Examiner’s rejection of claim 1 above.

a. *Markworth Fails to Disclose an Outer Sleeve that is Mechanically Coupled to a Frame as Recited in Element (ii)*

Element (ii) of claim 1 requires that the outer sleeve be mechanically coupled to the frame. In Appellants’ device, described above, the sleeve is mechanically coupled to the frame so that when the trigger is pulled, the inner shaft moves distally with respect to the sleeve which in turn pushes the grabber located on the distal end of the inner sleeve outside of the sleeve to its open position.

The cited sleeve 400 in Markworth is not mechanically coupled to the frame, but rather is connected to the distal end of the slide 300 for sliding movement. [Para. 48, 50.] The Examiner refers to this slide 300 as the “inner shaft” of the claims – not the frame – which would presumably correspond to body 200 in the Examiner’s scheme. Thus, according to the Examiner, this claim element is not met as the outer sleeve is not mechanically coupled to the frame, but instead is coupled to the inner shaft.

Claim 1, element (ii)	Examiner’s correspondence to Markworth
“outer sleeve mechanically coupled to the frame”	“outer sleeve” 400 is coupled to “inner shaft” 300 – not to the frame 200

As a result of Markworth teaching the opposite of the claim recitation – Markworth

works differently. According to the Examiner's reading of the elements, pulling the Markworth trigger pushes the "outer sleeve" distally to push on a spinal fixation rod – there can be no interaction with a "grabber." The rejection fails for this reason and claim 1 is patentable over Markworth.

b. Markworth Fails to Disclose an Inner Shaft Having a Grabber as Recited in Element (iii)

Element (iii) of claim 1 requires that the inner shaft have a grabber. As noted in the previous element, the grabber is located on the inner shaft so that pulling the trigger results in the inner shaft moving distally so that the grabber extends out of the outer sleeve to its open position (and consequently, when the trigger is released, the inner shaft and grabber are drawn into the outer sleeve and the grabber is closed).

The cited "grabber" 206 in Markworth is not on the "inner shaft" (slide 300, according to the Examiner). Rather, fingers 206 of Markworth (said to correspond to the "grabber") extend from the distal end of the body 200. [Para. 42.] The "grabber" 206 of Markworth does not extend from, nor is it coupled to, the "inner shaft" 300. The only element provided on the "inner shaft" 300 is the "outer sleeve" 400 – which does not "grab" anything, but rather pushes on a spinal fixation rod. Accordingly, this claim element is not met as "inner shaft" 300 does not have a "grabber" 206.

Claim 1, element (iii)	Examiner's correspondence to Markworth
"inner shaft having a grabber for mechanically engaging an implant"	"inner shaft" 300 carries "outer sleeve" 400; "grabber" 206 is not located on "inner shaft" 300

Again, as a result of Markworth teaching the opposite of the claim recitation – Markworth works differently. Because Markworth's grabber is not located on the inner shaft, the grabber cannot be operated by the trigger as further recited in claim 1. According to the Examiner's reading of the elements, pulling the Markworth trigger pushes the "outer sleeve" distally to push on a spinal fixation rod – there is no interaction with the "grabber" because the

“grabber” of Markworth is not on the “inner shaft” and thus does not relate to the trigger in any way. The rejection fails additionally for this reason and claim 1 is patentable over Markworth.

c. Markworth Fails to Disclose an Inner Shaft Slidably Disposed Within an Outer Sleeve as Further Recited in Element (iii)

Element (iii) of claim 1 goes on to expressly state that the inner shaft is slidably disposed within the outer sleeve. Because the inner shaft slides within the outer sleeve, it is able to push the grabber distally out of the outer sleeve to engage a prosthesis. The inner shaft and grabber can then be slidably retracted back into the stationary outer sleeve so that inner surfaces on the outer sleeve apply pressure to the grabber to cause it to close and thereby retain the prosthesis.

Markworth does not disclose such a relationship. The “inner shaft” 300 of Markworth is not slidably disposed within the “outer sleeve” 400 because the sleeve 400 is pivotally connected to the distal end of the “inner shaft” 300 – it does not and cannot slide with respect to it. [Para. 50.] Instead, because the “inner shaft” 300 and the “outer sleeve” 400 are pivotally connected, when the trigger of Markworth is actuated, both the “inner slide” 300 and the “outer sleeve” 400 advance distally *together* over the fingers 206 (said to correspond to the “grabber”) to act upon a spinal rod. Accordingly, this portion of the claim element is not met as the “inner shaft” 300 is not slidably disposed within the “outer sleeve” 400.

Claim 1, element (iii)	Examiner’s correspondence to Markworth
“the inner shaft slidably disposed along a major axis of the inner shaft within the outer sleeve”	the “inner shaft” 300 is pivotally connected to the “outer sleeve” 400 – not slidably disposed within it

According to the Examiner’s reading of the elements, the inner shaft is pivotally coupled to the outer sleeve causing both to advance together when actuated. Under this reading, the inner shaft cannot slide within the outer sleeve. The rejection additionally fails for this reason and claim 1 is patentable over Markworth.

d. Markworth Fails to Disclose that Actuation of a Trigger is Effective to Extend a Grabber from an Outer Sleeve to Thereby Release an Implant as Further Recited in Element (iii)

Still further in element (iii), claim 1 requires that actuation of the trigger extend the grabber from the outer sleeve to thereby release the implant. This operation is clearly described above with respect to the preferred embodiment of the invention, and, again, Markworth does the opposite. Rather than causing the grabber to extend from the outer sleeve and release the implant, squeezing the trigger of Markworth does not move the “grabber” 206 at all (the fingers remain still, gripping the pedicle screw). Instead, squeezing the trigger of Markworth causes the “outer sleeve” 400 to cover the “gripper” 206 – the opposite of the claim recitation.

Claim 1, element (iii)	Examiner's correspondence to Markworth
“whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant”	actuation of the trigger 500 does not move the “grabber” 206 at all – and actuation of the trigger 500 causes the “outer sleeve” 400 to cover the “grabber” 206 – further, there is no release

In response to Appellant’s arguments, the Examiner has continued to insist that the “grabber” of Markworth extends from the “outer sleeve” 400 upon actuation of the trigger 500:

Furthermore, the actuation of trigger, 514, does release the coupling element (see paragraph 0051, particularly lines 31-36). Thus, Markworth et al. disclose an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant, wherein the inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve, 400, **whereby actuation of the trigger, 514, extends the grabber from the outer sleeve to thereby release the implant.** [Emphasis added.]

The Examiner’s position is incorrect in many regards, and Markworth discloses the exact opposite of what claim 1 recites and the exact opposite of the Examiner’s characterization. First, squeezing the trigger 514 in Markworth does not move the grabber (fingers 206) at all. The very language in Markworth that the Examiner cites provides that as the trigger 514 is squeezed, the “outer sleeve” 400 and the “inner shaft” (slide 300) both advance together while the “grabber”

(fingers 206) stays in a fixed position. [Para. 51, lines 31-36.] The fingers 206 extend distally from the distal end of the body 200, which does not move at all when the trigger 514 is squeezed. Because fingers 206 do not move at all when the trigger 514 is squeezed, they certainly cannot move to extend from the outer sleeve.

Second, squeezing the trigger in Markworth pushes sleeve 400 over fingers 206. [Para. 51.] Rather than being configured to extend the grabber out of the outer sleeve upon actuation, Markworth does the opposite of the claim recitation and pushes the sleeve 400 *over* the fingers 206 when the trigger is actuated – Markworth’s fingers are within the sleeve under the exact conditions in which claim 1 requires the claimed grabber to extend out from the sleeve.

Third, actuating the trigger in Markworth does not “thereby release the implant,” and in fact does nothing to the relationship between the grabber and the implant. In Markworth, a force is applied to the body 200 to insert the implant between fingers 206. “The fingers 206 continue to grip” the implant as the spinal fixation rod is oriented, then, after the rod is placed, the user releases the grip of the “grabber” by rotating the instrument in its entirety. [Para. 51.] Again, this recited feature of element (iii) is not met by Markworth – Markworth provides the opposite.

The actual disclosure of Markworth is the exact opposite of what the Examiner says it is, and it is the exact opposite of what is recited in claim 1. The rejection further fails for this reason and claim 1 is patentable over Markworth.

e. *Markworth Fails to Disclose a Retaining Element for Directing the Grabber Toward a Closed Position as Recited in Element (iv)*

Turning to element (iv) of claim 1, the claimed device has a retaining element that directs the grabber to a closed position when the grabber is withdrawn into the outer sleeve. In the embodiment from the specification described above, the retaining element comprises inner surfaces on the outer sleeve that push the branches of the grabber closed when the grabber is withdrawn into the sleeve. The recited grabber mechanically engages the implant, in the embodiment from the specification, this happens by opening and closing the illustrated branches using the retaining element as the grabber extends out from and is withdrawn into the outer sleeve, respectively.

The Examiner asserts that springing connector 600 of Markworth corresponds to the

“retaining element for directing the grabber toward a closed position.” This assertion is incorrect for at least two reasons. First, the springing connector 600 of Markworth simply provides a biasing pressure in the direction of releasing the trigger. As noted several times above, the trigger of Markworth has no effect at all on the “grabber” and does not direct it to do anything. Rather, releasing the trigger (as the springing connector 600 biases toward) pulls both the “inner shaft” 300 and the “outer sleeve” 400 back towards the handle with no effect on “grabber” 206.

Further, to the extent that the Examiner may be implying (incorrectly in Appellant’s view) that sliding sleeve 400 over fingers 206 in Markworth means that the “grabber” is closed – Markworth does the opposite of that. The springing connector 600 of Markworth biases the Markworth device to retracting the slide 300 and sleeve 400 to leave the fingers 206 exposed – or “open” according to this hypothetical – not closed.

Claim 1, element (iv)	Examiner’s correspondence to Markworth
“a retaining element for directing the grabber toward a closed position”	a “retaining element” 600 directs an “outer sleeve” 400 to expose, rather than close, the “grabber” 206

The springing connector 600 does not correspond to the retaining element that directs the grabber, which mechanically engages the implant, to a closed position. Claim 1 is further patentable on this basis.

f. *Markworth Fails to Disclose a Grabber that is Substantially Contained Within an Outer Sleeve When a Trigger is Released as Recited in Element (iv)*

Element (iv) of claim 1 also recites that when the claimed trigger is released, the retaining element directs the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve. In the embodiment described above by reference to the specification, when the trigger is squeezed, the grabber extends distally from the outer sleeve to engage a prosthesis. As the trigger is released, the grabber is retracted back into the outer sleeve and inner surfaces of the outer sleeve (i.e., the retaining element) push on the outer surfaces of the grabber, directing it to a closed position in which the grabber is substantially contained within the outer sleeve.

Again, Markworth discloses the exact opposite. Referring to the very Figures cited by the Examiner, it is clear that releasing the trigger 514 (shown released, for example, in Figure 6A above) results in the proximal retraction of sleeve 400, thereby exposing fingers 206, which, as stated above, do not change their position in response to the actuation of trigger 514. Springing connector 600 applies pressure in the direction of releasing the trigger 514, which results in the fingers 206 being disposed outside of the sleeve 400 – not “substantially contained within the outer sleeve” as recited.

Claim 1, element (iv)	Examiner’s correspondence to Markworth
“whereby the grabber is substantially contained within the outer sleeve when the trigger is released.”	The “grabber” 206 is outside of the “outer sleeve” 400 when the trigger is released.

According to the Examiner’s reading of the elements, the grabber is not substantially contained within the outer sleeve when the trigger is released and instead is outside of the outer sleeve. For this additional reason, the rejection fails and there is no anticipation of claim 1.

At every turn, Markworth discloses, teaches, and suggests a structure that is the diametric opposite to that recited. Under these circumstances there can be no anticipation.

For all of these reasons, independent claim 1, as well as claims 2-7, 9, 11, 12, and 15 distinguish over Markworth and represent allowable subject matter. Allowance thereof is respectfully requested.

4. *Several Dependent Claims are Further Separately Patentable Over Markworth*

Dependent claims 3, 5, 6, 12, and 15 each depend directly from claim 1 and recite further features that are not disclosed, taught or suggested by Markworth. Accordingly, each of these claims stands separately with respect to claim 1 and with respect to each other.

a. *Dependent Claim 3 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Knob Mechanically Coupled to an Outer Sleeve and Causing the Outer Sleeve and Inner Shaft to be Rotated About the Frame*

Claim 3 depends from claim 1 and further recites a knob mechanically coupled to the outer sleeve and causing the outer sleeve and the inner shaft to be rotated about the frame. Markworth has no such structure, and permits no such rotation. First, the Examiner never identifies the “frame” of the instrument (though most likely it would correspond to body 200 in the Examiner’s scheme). The Examiner identifies “a knob, 712 . . . capable of causing the outer sleeve and the inner shaft to be rotated about the frame . . .” Tab 712 of Markworth is capable of no such thing. Tab 712 of Markworth (discussed in Para. 58 and illustrated in Figs. 7A and 7B) extends from the body 200 and provides ratchet teeth 708a for ratcheting the sliding of slide 300 with respect to body 200. In use, tab 712 is pressed downward to unlock the ratchet mechanism and has nothing to do with rotation. There is no possible way that the “outer sleeve” (sleeve 400 according to the Examiner) and “inner shaft” (slide 300 according to the Examiner) can rotate with respect to any frame (not identified by the Examiner, but possibly body 200) as recited because they slide linearly with respect to the body. Pressing tab 712 downward only results in the release of the ratchet and does nothing to the sleeve 400 or to the slide 300, much less cause them to rotate. Accordingly, claim 3 is separately patentable over Markworth on this basis.

b. *Dependent Claim 5 is Separately Patentable Over Markworth Because Markworth Fails to Disclose at Least One Protrusion on an Outer Sleeve*

Claim 5 depends from claim 1 and further recites at least one protrusion on the outer sleeve for slidably engaging a distraction instrument. The Examiner points to screw 112 as this protrusion. Screw 112 attaches sleeve 400 to slide 300. [Para. 50.] Screw 112 does not protrude and so cannot be said to anticipate “at least one protrusion.” Accordingly, claim 5 is separately patentable over Markworth on this basis.

c. *Dependent Claim 6 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Depth Control Member Slidably Coupled to an Outer Sleeve*

Claim 6 depends from claim 1 and further recites a depth control member slidably coupled to the outer sleeve for providing a predetermined insertion depth of the implant. The

Examiner identifies body 200 as the depth control member. As the position of body 200 of Markworth is fixed to the “grabber” (fingers 206 that extend from the distal end of the body), there is no way that the body can slide so as to provide a predetermined insertion depth of the implant – the body always has exactly the same orientation with respect to the implant. Accordingly, claim 6 is separately patentable over Markworth on this basis.

d. Dependent Claims 12, 13, and 14 are Separately Patentable Over Markworth Because Markworth Fails to Disclose a Grabber With at Least One Marking to Identify the Position of the Implant

Claim 12 depends from claim 1 and further recites that the grabber includes at least one marking to identify a position of the implant. The Examiner states that the “grabber further includes markings, e.g. 111, to identify a position of an implant. . .” There is no element numbered 111 in Markworth, and there is no feature on the external surface of the “grabber” of Markworth whatsoever. Accordingly, there is no marking on the grabber to identify the position of anything and claim 12, as well as claims 13 and 14 which depend from claim 12, is separately patentable over Markworth on this basis.

e. Dependent Claim 15 is Separately Patentable Over Markworth Because Markworth Fails to Disclose a Grabber that is Removably Coupled to an Inner Shaft

Claim 15 depends from claim 1 and further recites that the grabber is removably coupled to the inner shaft. The Examiner states that “the grabber is capable of being removably coupled to the inner shaft . . .” First, the claim is not premised in terms of capability. Second, the “grabber” of Markworth (fingers 206) never even touches the “inner shaft” (slide 300). The fingers 206 extend from the distal end of body 200 and fit within sleeve 400. They are not coupled to the inner shaft at all – much less removably. Accordingly, claim 15 is separately patentable over Markworth on this basis.

B. 35 U.S.C. §103(a) Rejection Over Markworth in View of Lim

Claim 13 is rejected pursuant to 35 U.S.C. §103(a) pursuant to Markworth in view of U.S. Patent Publication No. 2005/0055031 of Lim as explained in the Office Action:

Markworth et al. disclose the claimed invention except the marking being a pin. Lim discloses an implant implantation device and teaches the use of an indicator pin

to indicate the positioning of the clamping members relative to one another (see paragraph 0064). Since the grabber of Markworth et al. is elastic such that application of a force causes the fingers to separate (see paragraph 0042), it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Markworth et al. with the grabber including an indicator pin, in view of Lim, in order to indicate the positioning of the clamping members relative to one another.

As noted above, claim 13 depends from claim 12 which is separately patentable over Markworth. Also as indicated above, Markworth does not disclose any marker on the exterior of the grabber and Lim does not cure this deficiency. Lim simply discloses an implant inserter which is releaseably engageable to facilitate placement of the implant in a minimally invasive procedure. The indicator pin 152 of Lim is not located on a surface of a grabber as required by claim 13, but is located on a plate 128 located proximal to a “grabber” (engaging portion 121) and therefore does not satisfy the requirements of claim 13.

Further, the engaging portion 121 of Lim is operable by an actuator assembly to grasp and release an implant. An indicator pin 152 is therefore used on the plate 128 in order to monitor the position of the engaging portion 121 during a minimally invasive procedure. The “grabber” (fingers 206) of Markworth, however, is not independently operable by an actuator assembly and is only able to flex slightly when forced in order to grasp an implant. Thus, even if the indicator pin 152 was located in the correct place (which it is not), there would be no motivation to combine the indicator pin of Lim with the grabber of Markworth because there is no need for a user of the Markworth device to monitor the position of the fingers 206. For all of these reasons, claim 13 is separately patentable over Markworth in view of Lim.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

In the event that a petition for an extension of time is required to be submitted at this time, Appellant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-719.

Respectfully submitted,



Ronald E. Cahill
Reg. No. 38,403
Attorney for Appellant
NUTTER McCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2699
Telephone: (617) 439-2550
Facsimile : (617) 310-9550

Dated: October 24, 2007

CLAIMS APPENDIX

1. (Previously Presented) An implant device, comprising:
 - (i) a frame having a trigger mechanism;
 - (ii) an outer sleeve mechanically coupled to the frame;
 - (iii) an inner shaft having a grabber for mechanically engaging an implant, the inner shaft slidably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant; and
 - (iv) a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.
2. (Original) The device of claim 1, wherein the retaining element is a spring.
3. (Original) The device of claim 1, further including a knob mechanically coupled to the outer sleeve, the knob causing the outer sleeve and the inner shaft to be rotated about the frame.
4. (Original) The device of claim 1, further including a drag adjustment screw rotatably coupled to the frame for providing tension between the trigger mechanism and the inner shaft.
5. (Original) The device of claim 1, further including at least one protrusion on the outer sleeve for slidably engaging a distraction instrument.
6. (Original) The device of claim 1, further including a depth control member slidably coupled to the outer sleeve, the depth control member for providing a predetermined insertion depth of the implant.

7. (Original) The device of claim 1, wherein the grabber includes grabber tips for mechanically engaging the implant.
8. (Withdrawn) The device of claim 7, wherein the grabber tips are dovetailed in shape.
9. (Original) The device of claim 7, wherein the grabber tips include a first pair of slots for engaging a first engagement tab of the implant and a second pair of slots for engaging a second engagement tab of the implant.
10. (Withdrawn) The device of claim 9, wherein the first pair of slots are different in size from the second pair of slots.
11. (Original) The device of claim 9, wherein a sizing slot is located between the first pair of slots and the second pair of slots to allow for a variation of tab and slot dimensional differences.
12. (Original) The device of claim 1, wherein the grabber includes at least one marking to identify a position of the implant.
13. (Original) The device of claim 12, wherein the marking is a pin located on a surface of the grabber.
14. (Withdrawn) The device of claim 12, wherein the marking is a plurality of machined slots on a surface of the grabber.
15. (Original) The device of claim 1, wherein the grabber is removably coupled to the inner shaft.

16. (Withdrawn) An implant clip, comprising:
- (i) a first member;
 - (ii) a second member pivotally coupled to the first member, the coupling causing the implant clip to have a closed position and an open position;
 - (iii) a first implant holder, the first implant holder pivotally coupled to the first member; and
 - (iv) a second implant holder, the second implant holder pivotally coupled to the second member, a surface of the first implant holder and a surface of the second implant holder remaining substantially parallel to each other while the first member and the second member pivot between the closed position and the open position.
17. (Withdrawn) The implant clip of claim 16, wherein the first member and the second members are shells.
18. (Withdrawn) The implant clip of claim 16, wherein each holder defines a depression.
19. (Withdrawn) The implant clip of claim 18, wherein each depression is angled with respect to its holder.
20. (Withdrawn) The implant clip of claim 18, wherein each depression is made of a conformable material.
21. (Withdrawn) The implant clip of claim 16, further including a spring located between the first member and the second member, the spring directing the implant clip toward the closed position.

22. (Withdrawn) The implant clip of claim 16, wherein the second holder includes a pair of pins that slidably engage a respective pair of cylindrical cavities in the first holder, thereby causing the surface of each holder to remain substantially parallel to each other while the first member and the second member pivot between the closed position and the open position.

23. (Withdrawn) The implant clip of claim 16, wherein the first holder and the second holder includes a respective pin and a respective cylindrical cavity that slidably engage each other, thereby causing the surface of each holder to remain substantially parallel to each other while the first member and the second member pivot between the closed position and the open position.

24. (Withdrawn) The implant clip of claim 16, wherein each holder includes at least one alignment protrusion for aligning of an implantation instrument with the implant clip.

25. (Withdrawn) A method of inserting an implant, comprising the steps of:

- (i) loading an implant in an implant clip;
- (ii) mechanically engaging an implantation instrument to the implant; and
- (iii) removing the implant from the implant clip.

26. (Withdrawn) The method of claim 25, wherein the step of loading an implant in an implant clip includes:

- (i) opening the implant clip;
- (ii) inserting the implant into the implant clip; and
- (iii) closing the implant clip.

27. (Withdrawn) The method of claim 25, wherein the step of mechanically engaging the implantation instrument to the implant includes:

- (i) opening a grabber located on an end of the implantation instrument;
- (ii) aligning the grabber with the implant; and
- (iii) closing the grabber to mechanically engage the grabber to the implant.

28. (Withdrawn) The method of claim 25, further including the steps of:

- (iv) distracting a prepared disc space with a distraction instrument;
- (v) inserting the implant into the prepared disc space with the implantation instrument;
- (vi) releasing the implant from the implantation instrument; and
- (vii) removing the implantation instrument and distraction instrument.

29. (Withdrawn) The method of claim 28, wherein the step of inserting the implant into the prepared disc space includes aligning the implantation instrument with the distraction instrument.

30. (Withdrawn) The method of claim 25, wherein the implant is an artificial disc or a spinal fusion cage.

EVIDENCE APPENDIX

No evidence is being submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

1668276.1